

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION))) <hr/>	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION))	2:16 MD 1203
)	

Bartle, C.J. June 12, 2007

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In May 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician Michael J. Liston, M.D., F.A.C.C. Dr. Liston is no stranger to this litigation. According to the Trust, he signed 180 Green Forms in the same month that he signed claimant's Green Form and, as of August 31, 2003, in excess of 1,600 Green Forms overall on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated January 17, 2002, Dr. Liston attested in Part II of Mr. Banks' Green Form that he suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction that was less than 30%. Based on such

2(...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$507,887.

In the report of claimant's echocardiogram, Dr. Liston stated that claimant had "moderate mitral insufficiency with a regurgitant jet measuring 24% of total left atrial dimension." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Liston also stated that claimant's "left atrium measures 5.3 cm in the parasternal view and 6.8 cm in the apical four-chamber view." The Settlement Agreement defines an abnormal left atrial dimension as a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view or a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view. See id. § IV.B.2.c.(2)(b). Finally, Dr. Liston estimated claimant's ejection fraction as 20%, which meets the definition of a reduced ejection fraction under the Settlement Agreement. See id.

In November 2002, the Trust selected Mr. Banks' claim for review by Susan A. Mayer, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Mayer concluded that there was no reasonable medical basis for Dr. Liston's finding that claimant had moderate mitral regurgitation. According to Dr. Mayer, claimant had "mild mitral regurgitation by RJA/LAA and RJA > 1 cm from valve orifice." Dr. Mayer, however, concluded that there

was a reasonable medical basis for the attesting physician's findings of an abnormal left atrial dimension and a reduced ejection fraction.³

Based on Dr. Mayer's diagnosis of mild mitral regurgitation, the Trust issued a post-audit determination denying Mr. Banks claim.⁴ Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Audit Policies and Procedures § VI.⁵ The Trust then applied to the court for issuance of an Order to show cause why Mr. Banks' claim should be paid. On August 19, 2003, we

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of a reduced ejection fraction or an abnormal left atrial dimension, each of which is one of the conditions needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

4. Based on findings in audit, the Trust issues a post-audit determination regarding whether a claimant is entitled to Matrix Benefits.

5. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Mr. Banks' claim.

issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2979 (Aug. 19, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on October 23, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁶ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. See id. § VI.D.

6. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of his claim, Mr. Banks submitted an undated, unverified expert opinion from Steven J. Mattleman, M.D., F.A.C.C., who stated, in pertinent part, that:

After reviewing the study in detail, I have concluded that I agree with the interpretation of the attesting Cardiologist, and do not agree with the conclusion of the auditing Cardiologist. . . . I do not believe that [claimant's] mitral regurgitation as examined by the auditing physician is mild, but is moderate(RJA/LAA 23.8%).

Claimant also argues that the reasonable medical basis standard requires that an attesting physician's conclusions must be accepted unless the Trust proves that they were "irrational, foolish, senseless etc. from any medical perspective."

Therefore, according to claimant, because the Trust failed to prove that his attesting physician's finding of moderate mitral regurgitation was irrational, foolish or senseless, there is a reasonable medical basis for his claim. Claimant further argues that the auditing cardiologist did not follow the Settlement Agreement because she "eyeballed" the regurgitant jet area as

opposed to taking actual measurements, which, in his view, is required by the Settlement Agreement.

In reply, the Trust resubmitted Mr. Banks' claim to Dr. Mayer for a second review. Dr. Mayer confirmed her previous conclusion that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. In particular, Dr. Mayer stated: "In connection with my review of Claimant's entire tape, I again determined that Claimant's mitral regurgitation is mild. The planimetry relied upon by the Attesting Cardiologist and expert overestimated the [RJA] to [LAA] ratio by overtracing the mitral regurgitant jet area."

The Trust also disputes claimant's characterization of the reasonable medical basis standard and argues that a claim based on mitral regurgitation cannot be supported by a reasonable medical basis where the mitral regurgitant jet has been overtraced. The Trust further contends that Dr. Mayer complied with the Settlement Agreement in the manner in which she evaluated claimant's level of mitral regurgitation. Finally, the Trust asserts that claimant cannot meet his burden of proof simply by proffering an opinion from an additional physician.⁷

7. The Trust also argues that under Rule 26(a)(2) of the Federal Rules of Civil Procedure, physicians who proffer opinions regarding claims must disclose their compensation for reviewing claims and provide a list of cases in which they have served as experts. We disagree. We previously stated that Rule 26(a)(2) disclosures are not required under the Audit Policies and Procedures. See PTO No. 6997 (Feb. 26, 2007).

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation because his echocardiogram demonstrated only "mild mitral regurgitation." More specifically, Dr. Burke stated:

I found a technical limitation similar to Dr. Mayer, namely that the regurgitant jet area was overtraced on freeze frame images.

In the apical long axis view, I counted 3 beats with color flow Doppler in real-time imaging that were interpretable for MR assessment. I calculated a[n] RJA to LAA ratio of 14.1% on average - in the range for mild MR.

In the apical 4-chamber view, I counted 3 beats with color flow Doppler in real-time imaging that were interpretable for MR assessment. I calculated a[n] RJA to LAA ratio of 15.9% on average - in the range for mild MR.

In the apical two-chamber view, I again counted 3 beats with color flow Doppler in real-time imaging that were interpretable for MR assessment. I calculated a[n] RJA/LAA ratio of 11.8% on average - in the range for mild MR.

[T]his tape shows consistent assessment in the degree of mitral regurgitation - all in the mild MR range for parasternal long axis, apical 4-chamber, apical 2-chamber, and apical long axis views. The frozen images used to assess the degree of mitral regurgitation by the attesting and reviewing cardiologists result in an overestimation of the regurgitant jet area and hence the RJA/LAA ratio. Even taking into account inter-reader variability, I do not believe the mitral regurgitation in this echocardiogram can reasonably be read as moderate.

After reviewing the entire Show Cause Record before us, we find claimant's arguments without merit. First, and of crucial importance, claimant does not contest the analysis provided by either the auditing cardiologist or Technical Advisor.⁸ Claimant does not address Dr. Mayer's conclusion that claimant's attesting physician and expert overestimated his level of mitral regurgitation by overtracing the regurgitant jet area. Nor does claimant challenge Dr. Burke's specific findings that claimant's level of mitral regurgitation cannot reasonably be read as moderate and that claimant's physicians relied upon improper tracings. On this basis alone, claimant has failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

We also disagree with claimant's definition of reasonable medical basis. Without any discussion, claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962) and Black's Law Dictionary, 1538 (6th ed. 1990), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation where a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of

8. Despite an opportunity to do so, claimant did not submit any response to the Technical Advisor Report. See Audit Policies and Procedures § VI.N. Further, claimant did not seek leave to respond to the findings of Dr. Mayer following her second review of claimant's echocardiogram. See id. § VI.I.

"unreasonable" in Black's. One of the definitions, however, is "not guided by reason." The word "unreasonable" does not always mean "irrational" as claimant would have us believe and does not mean that here. We are not persuaded that either Gallagher or Black's supports claimant's position.

Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of those two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 21-22, 26 (Nov. 14, 2002). Here, Drs. Mayer and Burke determined, and claimant does not dispute, that claimant's physicians overtraced his regurgitant jet area and, thus, the resulting RJA/LAA ratio was overestimated. Such an

unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

Finally, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as "20%-40% RJA/LAA," which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation.⁹ As we explained in PTO No. 2640, "[e]yeballing' the regurgitant jet to assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15 (Nov. 14, 2002).

While claimant relies on the Settlement Agreement's use of the word "measured" in the definition of "FDA Positive," its meaning must be considered in the context of the phrase "by an echocardiographic examination," which immediately follows it. See Settlement Agreement § I.22. In its entirety, the phrase placed at issue by claimant is "measured by an echocardiographic examination." This phrase does not mean that actual measurements for assessing the level of mitral regurgitation are required. To

9. Claimant's argument also is flawed because the Technical Advisor, although not required to, made a specific measurement of the level of mitral regurgitation which further establishes that claimant is not entitled to Matrix Benefits.

the contrary, a claimant's level of regurgitation must be determined based on an echocardiogram, as opposed to other diagnostic techniques. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.¹⁰

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Mr. Banks' claim for Matrix Benefits.

10. We have found consistently that "eyeballing" is an acceptable echocardiographic practice under the Settlement Agreement. See PTO No. 6339 at 9-10 (May 25, 2006).

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	
)	

PRETRIAL ORDER NO.

AND NOW, on this 12th day of June, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the final post-audit determination of the AHP Settlement Trust is AFFIRMED and the Level II Matrix claim submitted by claimant, Kenneth Banks, is DENIED.

BY THE COURT:

/s/ Harvey Bartle III

C.J.